DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 21 1993

resent 2/1/93
at PTO's request

Re: VANTIN® Tablets
Docket No. 93E-0009

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,486,425 filed by Sankyo Co. Ltd. under 35 U.S.C. § 156. The human drug product claimed by the patent is VANTIN® Tablets (cefpodoxime proxetil), which was assigned New Drug Application (NDA) No. 50-674.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the active ingredient, cefpodoxime proxetil.

The NDA was approved on August 7, 1992, which makes the submission of the patent term extension application on December 7, 1992, untimely within the meaning of 35 U.S.C. § 156(d)(1). However, the applicant "requests that [the] application be considered as timely filed since the failure to file within sixty (60) days was unintentional." Patent Term Extension Application, p. 2. The applicant claims that due to a misunderstanding between it and its U.S. licensee, The Upjohn Company, applicant was not aware that the patent extension application had not been filed until December 4, 1992. Id., at Appendix F, p. 1. Therefore, applicant requests that the deadline for filing be extended to February 2, 1993, which is sixty (60) days after December 4, 1992. Id., at 2.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Lawrence T. Welch